

REMARKS

By this Office Action, the Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

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| Group I     | Claims 1-3, 17-19 and 21, drawn to an isolated polypeptide and a medicament comprising said polypeptide identified as SEQ ID NO: 1, classified in class 530, subclass 350.   |
| Group II.   | Claims 4-6, 17-19 and 21, drawn to an isolated or recombinant nucleic acid molecule, SEQ ID NO: 2 and a medicament comprising said sequence, classified in class 536, subclass 23.5.   |
| Group III.  | Claim 7, drawn to a method for screening and/or diagnosing breast cancer comprising detecting and/or quantifying an amount of a polypeptide identified as SEQ ID NO: 1, classified in class 435, subclass 7.1.   |
| Group IV.   | Claim 7, drawn to a method for screening and/or diagnosing breast cancer comprising detecting and/or quantifying an amount of a nucleic acid identified as SEQ ID NO: 4, classified in class 435, subclass 6.  |
| Group V.    | Claims 8-10, 17-19 and 21, drawn to an antibody that binds SEQ ID NO: 1 and a medicament comprising said antibody, classified in class 530, subclass 387.3.  |
| Group VI.   | Claims 11-15, drawn to a method of screening for agents capable of interacting with a polypeptide identified as SEQ ID NO: 1, classified in class 436, subclass 64.  |
| Group VII.  | Claims 16-19 and 21, drawn to an agent which alters the expression and/or activity of a polypeptide identified as SEQ ID NO: 1 and medicament for use in prophylaxis and/or treatment of cancer comprising an agent capable of modulating the expression and/or activity of said polypeptide, classified in class 436, subclass 94.1.      |
| Group VIII. | Claims 16-19 and 21, drawn to an agent which alters the expression and/or activity of a nucleic acid identified as SEQ ID NO: 2 and medicament comprising an agent capable of modulating the expression and/or activity of a nucleic acid molecule which has substantial identity to SEQ ID NO: 2, classified in class 424, subclass 1.73. |
| Group IX.   | Claim 20, drawn to a method for prophylaxis and/or treatment of breast   |

cancer comprising administering a polypeptide identified as SEQ ID NO: 1, classified in class 424, subclass 9.1.

Group X. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering a nucleic acid having substantial identity to SEQ ID NO: 2, classified in class 424, subclass 64.

Group XI. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an antibody, classified in class 424, subclass 178.1.

Group XII. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an agent capable of modulating the expression of a polypeptide identified as SEQ ID NO: 1, classified in class 424, subclass 9.1.

Group XIII. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an agent capable of modulating the expression of a nucleic acid molecule identified as SEQ ID NO: 2, classified in class 424, subclass 1.73.

Responsive to the Requirement for restriction, Applicants elect to prosecute the invention of Group I, with traverse, Claims 1-3, 17-19 and 21, which are drawn to an isolated polypeptide and a medicament comprising said polypeptide identified as SEQ ID NO: 1, classified in class 530, subclass 350.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. Claim 7 of Group III is drawn to a method for screening and/or diagnosing breast cancer comprising detecting and/or quantifying an amount of a polypeptide identified as SEQ ID NO: 1, which is fundamentally related to Claims 1-3, 17-19, and 21 of Group I, drawn to an isolated polypeptide and a medicament comprising said polypeptide identified as SEQ ID NO: 1. The search for any of the methods separately classified by the Examiner as the invention of Group III would require an additional search of the **identical** classes wherein the claims of Group I are classified, thus resulting in a duplicate search for the same material. Thus, Applicants submit that the Search and Examination of Group III with Group I can be made without serious burden, and therefore the Examiner should examine the claims of these groups on the merits.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of the Claims of Groups I and III of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the Claims drawn to Group III and Group I is in order.

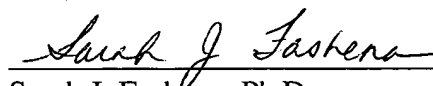
No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

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In view of the above, an early action on the merits of the Claims is courteously solicited.

Respectfully submitted,

A handwritten signature in cursive script, reading "Sarah J. Fashena", is written over a horizontal line.

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